Exercising Your
Ethics

By Tambra Thomas

Maintaining ethics and data integrity in a laboratory setting

Does your laboratory have an "ethical muscle?" Do you feel your employees are flexing this muscle? Ethics and data integrity should be an integral part of your laboratory's quality assurance program. Just as peanut butter and jelly or milk and cookies go together, so do ethics, data integrity and quality. It is a logical concept, but it can be easy to overlook.

We are soon embarking on a new year. Make it your laboratory's resolution to bring the topics of ethics and data integrity to a whole new level.

Strong Work Ethic

Having a good work ethic means being responsible, reliable, always willing to go above and beyond, and generally putting forth your best effort to get the work done. I would argue it also means being honest and forthright in the workplace.

It does not matter what your job actually entails—what matters is that you have a sense of right and wrong as it applies to your role. If something does not seem right, do you question it? Do you report it to the appropriate person? Maybe you run across a situation with your work that causes you to question whether it is acceptable to do it a particular way. Do you ask questions when you are unsure?

Let's take this topic to the next level. Consider how ethics relate to data integrity for laboratories. Having an appropriate work ethic leads to making sound ethical decisions, which in turn leads to the production of good quality data in laboratories. Good quality data are critical—to the customers, to the environment and to the community—when they specify contaminant levels in drinking water, for instance.

Good quality data also are critical for trust—trust from the laboratories' customers and from your coworkers and management team.

Employees' Role

This leads us to ask, "How can I have a solid ethics and data integrity program for my laboratory?" The goal for a solid ethics and data integrity program—one to which your laboratory can fully commit—is to "train and sustain."

Employees must have a strong moral compass, especially when dealing with data, in order to understand how to do the right thing. If there is a question about the procedure they are performing, they need to ask it. If something does not make sense to them, they need to ask about it. Especially critical is that they practice the true corrective action if their data do not pass the assigned quality control criteria. It may mean troubleshooting the procedure and checking for errors in analysis. It also may mean starting over from square one.

There may be tremendous pressure to finish an analysis and get the data out the door to the customer. Maybe there is a deadline that must be met for a research project, or your boss is counting on you to finish a project in order to obtain funding for his or her next research endeavor. These situations make it tempting to cut corners to get the job done. Employees need to know it is never the right decision to cut corners or otherwise alter data in order to make them acceptable.

Employees in the laboratory first need to be trained on how to correctly produce and review their data, and then on how to recognize data that are of questionable quality. Third, they need

to bring forward possible issues with their data and have enough integrity in their work not to alter them in any way that is unacceptable. Training is one key to producing quality data. Another is finding employees that have their moral compasses in alignment.

Managers' Role

At the other end of the spectrum, managers have the moral duty to uphold their end of the bargain. Managers are not necessarily immune to the pressures of getting work done at any cost. Assuming they are ethical employees themselves, how can they portray the importance of ethics and data integrity to their teams? In addition, how do they train and sustain? It does not have to be a complex process if you do not want it to be.

Train your employees not only on the importance of ethics and data integrity, but also on how to be aware of "flexing their ethical muscles" in the laboratory. Inform and empower them to make the right choices, then sustain this effort by making ethics and data integrity a crucial part of your quality system.

Let's first consider how to train employees. Teach them about the ways that data can be compromised. A few examples include improper manual integration, dry labbing or unwarranted manipulation of computer software. Once they understand the acceptable ways of dealing with their data, they can then apply their own moral compasses to ensure data integrity.

An excellent way to accomplish training is to have a formal training session about ethics and data integrity as part of the new hire process. A formal policy regarding ethics and data integrity also is a good idea. In addition, conduct a yearly refresher on this subject for all members of your team. Document the training in an effort to hold them accountable for any infractions.

Next, sustain this effort by always following your lab's ethics and data integrity policy. If you do not have one, then start the new year on solid ground by making one. For the quality assurance managers out there, an excellent way of achieving this is to perform periodic monitoring

of data integrity. This could consist of many things, such as spot checking data for inconsistencies or errors, checking for completion of documentation and examining data involving manual integrations when dealing with chromatograms.

You also may sustain data integrity by performing internal audits of your laboratory. This may mean an audit of the entire quality systems program or of a particular area of concern. It is always a good practice to document all findings and determine corrective action if needed. If corrective actions are required, sustain this effort by always following up to ensure the action is being carried out.

I like to regard data integrity as the scientists' golden rule. When determining if data are good quality, think in these terms: Ensure the work was performed, can be authenticated, can be reconstructed and is traceable. In addition, document everything. Further, do not

release data until you are confident in their quality. This applies to those producing the data as well as those reviewing it. We are all in this together—just as it takes a village to raise a child, it takes the entire laboratory team to ensure a superior ethics and data integrity program.

The bottom line is that if you are a manager, encourage your team to flex its ethical muscles. If you are a member of the team, challenge yourself to flex your own ethical muscles by fully participating in your laboratory's ethics and data integrity program. Accept nothing less than the best from yourself and others—it's that simple. *wqp*

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